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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|------------------------|---------------------|------------------|
| 10/085,000 | 03/01/2002 | Werner Josef Frantsits | W5-121002-pUS | 3705 |

466 7590 06/24/2002

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| EXAMINER |
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KWON, BRIAN YONG S

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| ART UNIT | PAPER NUMBER |
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1614

DATE MAILED: 06/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/085,000

Applicant(s)

FRANTSITS, WERNER JOSEF

Examiner

Brian S Kwon

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/460,769.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application

Acknowledgment is made of applicant's filing of the instant application as a continuation of copending application Serial No. 09/460,769.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kolter et al. (US 5891907) in view of Caloianu et al. (RO 113211) and End et al. (US 5453447).

The claims read on a process of preparing an aqueous formulation comprising 0.1-10% betacarotene, 10-40% polyoxyethylene-660-hydroxystearate, 5-20% isopropyl myristate and at least one of ascorbyl malmitate and alpha-tocopherol. Further limitations include 15-20% (w/v) of polyoxyethylene-660-hydroxystearate in claim 3; 1-5% (w/v) beta-carotene in claim 5; 5-10%

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(w/v) of isopropyl myristate in claim 7; 0.01-1.0% (w/v), more specifically 0.02-0.3% (w/v), of the antioxidant in claims 8-9; 0.005-0.15% (w/v), more specifically 0.01-0.15%, of each ascorbyl palmitate and alpha-tocopherol in claims 10-11; 5mg/ml of benzyl alcohol as the additional ingredient in the composition in claims 12-13.

Kolter teaches a stable aqueous formulation of beta-carotene in 0.1-10% (w/v), comprising polyoxyethylene-12-hydroxystearate with 10 to 40 oxyethylene units (Solutol H15), which is the same as polyoxyethylene-660-hydroxystearate or polyoxyethylene-660-12-hydroxystearate, in 1-40% (w/v), more preferably 5 to 25%, and tocopherol in 0.1-20% (w/v). See abstract; Examples; Claims 1-9. Kolter also teaches a process of making stable aqueous solubilizes, which comprises briefly heating the non-ionic emulsifier (e.g., Solutol HS 15) with the lipophilic vitamin or vitamin derivatives at above 120°C. Then while stirring, beta-carotene is introduced, the heating is removed and a solution of antioxidants in water for injections at about 20°C is added to the desired final concentration of 0.1-10% stable aqueous beta-carotene formulation (See Example 1).

Caloianu teaches the use of 2-5% isopropyl myristate and 0.01-0.1% vitamin E in 0.01-0.05% beta-carotene containing composition.

End teaches process of making 0.5-6% beta-carotene formulation by briefly heating beta-carotene together with a nonionic emulsifier (e.g., ethoxylated monhydroxystearic acid with 15 oxyethylene units) to give a homogeneous solution at above 120°C with or without the addition of 0.1-10% of antioxidants (e.g., DL-alpha-tocopherol), rapidly cooling it to below 100°C by adding water, and subsequently adjusting to the desired final concentration of beta-carotene with the addition of benzyl alcohol as a preservative at between 10° and 80°C (column 2, lines 11-48).

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Kolter's teaching differs from the claimed invention in 1) the use of isopropyl myristate as an additional mediator of solubility; 2) benzyl alcohol as a preservative; and 3) the specific concentration of secondary ingredients in the formulation (e.g., isopropyl myristate, ascorbyl palmitate and alpha-tocopherol). To incorporate such teaching into the teaching of Kolter, would have been obvious in view of Caloianu who teaches the use of isopropyl myristate as an emulsifier of beta-carotene and End who teaches the use of benzyl alcohol as a preservative for beta-carotene formulation.

The above references in combination make clear that the process of making the aqueous formulation of the claimed range of beta-carotene (0.1-10%) containing 10-40% polyoxyethylene-660-hydroxystearate, 0.1 to 20% tocopherol and/or ascorbic acid or ascorbate is old and well known. The above references also make clear that the use of isopropyl myristate, ascorbyl palmitate, DL-alpha-tocopherol and benzyl alcohol as secondary agents in the aqueous beta-carotene formulation is old and well. The mere addition such secondary agents to the beta-carotene formulation is well considered within the skill of the artisan, absent evidence showing the unexpected results. In addition, optimization of amounts of known active and inactive ingredients in a composition is well considered within the skill of the artisan, and the artisan would be motivated to determine optimum amounts to get maximum effect of the drug.

One skilled in the art would have been motivated to combine the teaching of above reference such that the enhanced, stable beta-carotene formulation could be prepared.

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703)308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Brian Kwon

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1600

A handwritten signature in black ink, appearing to read "Zohreh Fay", is written below the printed name.